REMARKS

Entry of the foregoing amendments, reconsideration and re-examination of the subject application, as amended, pursuant to and consistent with 37 CFR §1.112, and in light of the remarks which follow, are respectfully requested.

By the present amendment, claim 17 has been amended to incorporate the features of claim 20 and 24, and to further specify that the therapeutic agent is deliverable within 1 mm of a target site (finding support in original Claim 10) and to further specify that the therapeutic agent is nucleic acid, protein or polypeptide therapeutic agent. Support for this feature may be found at pages 5-6 of the specification *et seq*.

Further, new dependent claims 25-29 are presented which further provide for specific types of therapeutic agents (finding support at pages 5-6 of disclosure) for the metal seed to be constituted of specific metals or alloys (finding support at the paragraph bridging pages 8-9), and for the further incorporation of a radionuclide (finding support at pages 5-6 of the specification).

Turning now to the Office Action, Applicants confirm their previous Election.

The objection to "GeneSeed" is noted. Applicants have capitalized this term as suggested by the Examiner at all occurrences to overcome the objection.

Claim 23 stands rejected under 35 USC §112 first paragraph as being broader than the enabling disclosure. Essentially, the Examiner alleges that the specification only enables hollow seed drug delivery systems constituted of titanium. This rejection is respectfully traversed.

The specification makes abundantly clear that the invention is applicable with any biocompatible metal, among which a large number are identified in the paragraph bridging pages 8-9 of the disclosure. While titanium is preferred (because of cost), there is absolutely no basis for assuming that it is essential to the invention. Nor is there any basis for concluding that equivalent metal seeds cannot be produced using other metals and metal alloys. Indeed, titanium is only exemplary of suitable metals that may be utilized. Withdrawal of the enablement rejection of Claim 23 is therefore respectfully requested.

Claim 18 stands rejected on the basis that the specification only enables the use of viruses as the nucleic acid sequence which may be encapsulated in the metal seed. The position of the Examiner is respectfully traversed.

To the contrary, the specification exemplifies the use of radiation sensitizing genes (p. 6, line 13), as well as antisense nucleic acid sequences, ribozymes, viruses, plasmids, and viral vectors as examples of potential therapeutic nucleic acid sequences which may be encapsulated in the drug delivery devices according to the invention. The Examiner is referred in particular to the disclosure at page 15, lines 7-13, as well as original claims 12, 13, and 15. Withdrawal of this rejection is respectfully believed to be in order.

Claims 17-23 stand rejected under 35 USC §112 second paragraph as being indefinite. This rejection is respectfully traversed to the extent it may be applicable to the claims as amended.

The rejection of "small" is moot as the dimensions of the device are now recited from original claim 20.

The objection to "target" is also moot as the claim now recites a targeted site in tissue or organ.

Finally, the objection to "high precision" is moot as the meaning of this phrase is now explicitly recited in Claim 17.

Based on the foregoing, this application is believed to be in condition for allowance.

A notice to that effect is respectfully solicited.

If the Examiner has any questions relating to this application, she is respectfully requested to contact the undersigned.

Respectfully submitted,

PILLSBURY WINTHROP LLP

By: 

Robin L. Teskin
Registration No. 35,030

1600 Tysons Boulevard
McLean, VA 22102
703.905.2200

Date: December 18, 2001

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MARKED-UP COPY OF CLAIMS

17. (Amended) A drug delivery system that comprises the following:

(i) a [small] hollow metal "seed" that has a diameter ranging from about 0.004 to 0.4 inches, a length ranging from about 0.002 to 3 inches, and a wall thickness ranging from about 0.0005 to 0.5 inches that can be [of a size that allows for it to be] inserted into a target in a tissue or organ site *in vivo* [site] with high precision, wherein high precision means that the hollow seed is placed within about 1 millimeter of a target site in a tissue or organ, and having encapsulated therein

(ii) at least one nucleic acid sequence, protein or polypeptide containing therapeutic agent, and

(iii) [further] having disposed therein one or more holes of a diameter that provide [allow] for the controlled diffusion of [said] the encapsulated nucleic acid sequence protein or polypeptide containing therapeutic agent.